

DEXIFOL- ascorbic acid, folic acid, biotin, thiamine hydrochloride, riboflavin, niacinamide, pyridoxine hydrochloride, cyanocobalamin, and calcium pantothenate tablet, film coated
Taleos Pharma

DEXIFOL Caplets

Rx Only

DESCRIPTION

DEXIFOL is a prescription multi-vitamin in the form of a dark yellow, film-coated, caplet.

INDICATION AND USAGE

DEXIFOL is a prescription multi-vitamin supplement that can be taken to improve nutritional status in conditions requiring dietary supplementation. DEXIFOL can also be used for the dietary management of individuals with distinct nutritional needs under a physician or healthcare provider's supervision for end stage failure, dialysis, hyperhomocysteinemia or inadequate dietary vitamin intake.

CONTRAINDICATIONS

This product is contraindicated in patients with a known hypersensitivity to any of the ingredients.

WARNING

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematological remission can occur while neurological manifestations remain progressive. Folic Acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B12 is deficient.

DO NOT EXCEED RECOMMENDED DOSAGE.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

PRECAUTIONS

Folic Acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematological remission can occur while neurological manifestations remain progressive. The 1 mg of cyanocobalamin contained in DEXIFOL Caplets has been shown to provide an adequate amount of cyanocobalamin to address this precaution. A safer upper limit of 100 mg per day has been established for the unsupervised medical use of pyridoxine. Consider all sources of pyridoxine supplementation when prescribing DEXIFOL Caplets.

If pregnant, or planning to become pregnant or are currently breast-feeding please contact your physician, or healthcare provider before using or continuing use of this medication.

ADVERSE REACTIONS

Allergic sensitization has been reported following both oral and parenteral administration of folic acid. Paresthesia and somnolence have been reported with the use of pyridoxine hydrochloride. Mild transient diarrhea, polycythemia vera, peripheral vascular thrombosis, itching transitory exanthema and feeling of swelling of the entire body has been associated with the use of cyanocobalamin.

DRUG INTERACTIONS

Pyridoxine supplements should not be given to patients receiving the drug levodopa, because the action of levodopa is antagonized by pyridoxine. However, pyridoxine may be used concurrently in patients receiving a preparation containing both carbidopa and levodopa. Concurrent use of phenytoin and folacin (folic acid) may result in decreased phenytoin effectiveness.

DOSAGE AND ADMINISTRATION

Adults

One caplet taken orally daily or as directed by a physician.

DO NOT EXCEED RECOMMENDED DOSAGE.

Supplement Facts

Serving Size: 1 Caplet	Servings per Container: 30	
Amount Per Serving	% Daily Value	
Vitamin C (as Ascorbic Acid)	60mg	100%
Folic Acid (as Folic Acid - AbsoFol™)*	5mg	1,250%
D-Biotin	300mcg	100%
Vitamin B1 (as Thiamine HCl)	1.5mg	100%
Vitamin B2 (as Riboflavin)	1.5mg	88%
Vitamin B3 (as Niacinamide)	20mg	100%
Vitamin B6 (as Pyridoxine HCl)	50mg	2,000%
Vitamin B12 (as Cyanocobalamin)	1mg	16,667%
Pantothenic Acid (as Calcium Pantothenate)	10mg	100%

* AbsoFol™, under exclusive license, is trademark of Taleos Pharma Corp. (patents pending)
DEXIFOL and TALEOS are trademarks of Taleos Pharma Corp.

STORAGE

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [See USP Controlled Room Temperature.]

Protect from light and moisture.

Dispense in a well-closed, tight, light-resistant container as defined by the USP using a child resistant closure.

HOW SUPPLIED

DEXIFOL caplets are supplied as dark yellow, oblong, film coated caplets. DEXIFOL caplets are available in bottles of 30 (NDC: 70877-1002-01).

Distributed By:

Taleos Pharma Corp.

Eatontown, NJ 07724

www.taleos-pharma.com

PRINCIPAL DISPLAY PANEL - 30 Caplet Bottle Label

70877-1002-1

DEXIFOL

PRESCRIPTION
MULTI-VITAMINS

WITH 100%
AbsoFol

Rx Only
30 CAPLETS

DIETARY SUPPLEMENT

DOSAGE AND ADMINISTRATION: One caplet taken orally once a day, or as directed by a physician. Consult with your healthcare professional if you are pregnant or nursing.

STORAGE: Store at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F). See USP Controlled Room Temperature. Protect from light and moisture.

KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN

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Eatontown, NJ 07724 www.taleos-pharma.com



MADE IN USA



Lot No. TA9731A

Exp. Date: 12/2019



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Other Ingredients: Dicalcium Phosphate, Microcrystalline Cellulose, Croscarmellose Sodium, Hypromellose, Stearic Acid, Titanium Dioxide, Sodium Lauryl Sulfate, Magnesium Silicate, Triacetin, Magnesium Stearate and Mineral Oil.

DEXIFOL

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Product Information

Product Type	DIETARY SUPPLEMENT	Item Code (Source)	NHRIC:70877-1002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Ascorbic Acid (UNII: PQ6CK8PD0R) (Ascorbic Acid - UNII:PQ6CK8PD0R)	Ascorbic Acid	60 mg
Folic Acid (UNII: 935E97BOY8) (Folic Acid - UNII:935E97BOY8)	Folic Acid	5 mg
Biotin (UNII: 6SO6U10H04) (Biotin - UNII:6SO6U10H04)	Biotin	300 ug
Thiamine Hydrochloride (UNII: M572600E5P) (Thiamine ion - UNII:4ABT0J945J)	Thiamine Hydrochloride	1.5 mg
Riboflavin (UNII: TLM2976OFR) (Riboflavin - UNII:TLM2976OFR)	Riboflavin	1.5 mg
Niacinamide (UNII: 25X51I8RD4) (Niacinamide - UNII:25X51I8RD4)	Niacinamide	20 mg
Pyridoxine Hydrochloride (UNII: 68Y4CF58BV) (PYRIDOXINE - UNII:KV2JZ1B16Z)	Pyridoxine Hydrochloride	50 mg

Cyanocobalamin (UNII: P6YC3EG204) (Cyanocobalamin - UNII:P6YC3EG204)	Cyanocobalamin	1 mg
Calcium Pantothenate (UNII: 568ET80C3D) (Pantothenic Acid - UNII:19F5HK2737, Calcium Cation - UNII:2M83C4R6ZB)	Pantothenic Acid	10 mg

Inactive Ingredients

Ingredient Name	Strength
ANHYDRO US DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
Microcrystalline Cellulose (UNII: OP1R32D61U)	
Croscarmellose Sodium (UNII: M28OL1HH48)	
Hypromellose 2910 (15 mpa.s) (UNII: 36SFW2JZ0W)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Titanium Dioxide (UNII: 15FIX9V2JP)	
Sodium Lauryl Sulfate (UNII: 368GB5141J)	
Magnesium Silicate (UNII: 9B9691B2N9)	
Triacetin (UNII: XHX3C3X673)	
Magnesium Stearate (UNII: 70097M6I30)	
Mineral Oil (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:70877-1002-1	30 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
DIETARY SUPPLEMENT		11/01/2017	

Supplement Facts

Serving Size :		Serving per Container :
Amount Per Serving	% Daily Value	
color		
scoring	1	
shape		
size (solid drugs)	22 mm	

Labeler - Taleos Pharma (080318529)